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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,385	08/08/2001	Leslie Dennis Michelson	16602.003	2406

28381 7590 01/10/2005

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EXAMINER

KALINOWSKI, ALEXANDER G

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 01/10/2005

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/923,385
Filing Date: August 08, 2001
Appellant(s): MICHELSON ET AL.

Joseph Micallef, Reg. No. 39,772
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/14/04.

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(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 14 and 15 stand rejected under 35 USC 112(second paragraph) and

Claims 2-15 and 129-151 stand rejected under 35 USC 103(a).

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

Appellant's brief includes a statement that claims 2-15 and 129-151 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

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(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

2002/0099570 A1

Knight

7-2002

Anonymous, information available at the web site of CenterWatch, 12/5/1998, 13 pages.

Larkin, Marilyn, "Where to find clinical trials on the Web", The Lancet, April 11, 1998,

Vol. 31, No. 9109, page 1140.

Anonymous, "TVisions Wins Top Web Externet Award: recognized for Creative Life-Saving Site", Business Wire, 7/1/1999, No. 42844318, page 1.

Baldwin, Gary, "System makes it easier to link patients to clinical trials", American

Medical News, 11/16/1998, Vol. 41, No. 53, pp. 25.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 includes the limitation of "other off-line sources". This is indefinite in that Applicant has listed specific offline sources in the claim limitation yet

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uses the phrase "other off-line sources". For purposes of applying prior art, the Examiner will not consider the phrase "other off-line sources".

3. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner cannot determine the scope of the claim limitation of "the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database". Is the person or caregiver required to present genetic sequence information when the person or caregiver registers with the database in step a) ? If so, then the claim contains a missing step since this information is not included in the claimed registration step. Or is the disease condition of interest that is input by the person or caregiver during the registration process of step a) associated with a particular genetic sequence information? Or are there clinical trials related to specific studies relating genetic sequence information to a specific diseases that relate to the patient's or caregiver's disease condition of interest as submitted during the registration step a)? For purposes of applying prior art, the Examiner, as best understood by a reading of the specification, will interpret this limitation as matching patients with a clinical study that is attempting to relate genetic sequence information to a disease.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 4-14 and 130-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, Gary, "System makes it easier to link patients to clinical trials"(hereinafter Baldwin" in view of information available at the website of CenterWatch (hereinafter CenterWatch) and Knight, Pub. No. 2002/0099570.

As per claim 2. Baldwin discloses a method for recruiting a person to participate as a subject in a clinical study (i.e. link patients to clinical trial)(title and abstract), comprising the steps of.

- (a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database (i.e. AOR Securenet is a secure externet ... patient information is entered online...)(page 2), wherein the registration information includes at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators ...)(page 2-3);
- (b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information (see entire article);
- (c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person (i.e. ... if fuzzy match is made, an email alert with online link to trial information

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is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators...)(pages 2-3);

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician... open to select users. Clinicians, drug companies and administrators ...)(pages 2-3);

Baldwin does not explicitly disclose

wherein the registration information includes at least a geographic location of the person.

However, CenterWatch discloses wherein the registration information includes at least a geographic location of the person (i.e. Patient Notification Service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the registration information includes at least a geographic location of the person and automatically presenting a questionnaire associated with the given clinical study to the person or caregiver as disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

Baldwin and CenterWatch do not explicitly disclose

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d).

(f) storing answers submitted by the person or caregiver in the database .

However, Knight discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) (i.e. trial specific questions)(Fig. 1, Fig. 8, and paragraph 70). Knight also discloses storing answers

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submitted by the person or caregiver in the database (i.e. patient database)(paragraphs 114-125). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As per claim 4, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study.

However, Knight discloses wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study ((i.e. trial specific questions)(Fig. 1, Fig. 8, and paragraph 70). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As per claim 5, Baldwin and CenterWatch do not explicitly disclose The method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (page 2).

However, Knight discloses wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or

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more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (paragraphs 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As per claim 6, Baldwin discloses the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site (Fig. 10 and Fig. 11).

As per claim 7, Baldwin discloses The method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver (page 2).

As to claim 8, Baldwin, CenterWatch, and Knight do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.

However, the Examiner takes official notice that it was well known in the electronic arts to send requested notice information via mail. The motivation for

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delivering notice by regular mail is for the convenience of the requestor. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the notice provided in step (d) is sent by regular mail to the person or caregiver within the Baldwin, CenterWatch and Knight combination for the motivation stated above.

As to claim 9, Baldwin, CenterWatch and Knight do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver.

However, the Examiner takes official notice that it was well known in the electronic arts to send notice information by telephone to a requestor. The motivation for delivering notice by telephone is for the convenience of the requestor. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the notice provided in step (d) is communicated by telephone to the person or caregiver within the Baldwin, CenterWatch and Knight combination for the motivation stated above.

As per claim 10, Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.

However, Baldwin does disclose wherein a determination is made to provide the person or caregiver with the notice in step (c) as discussed previously above.

CenterWatch discloses providing notice of clinical studies in accordance with a

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geographic location of the given clinical study (CenterWatch Patient Notification service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include notice of clinical studies in accordance with a geographic location of the given clinical study as disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As per claim 11, Baldwin discloses The method of claim 2, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study (i.e. fuzzy matches. The Examiner interprets this feature to read on clinical trials that the person or caregiver does not match)(page 2).

As per claim 12, Baldwin discloses The method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies (page 2).

As per claim 13, Baldwin does not explicitly disclose The method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.

However, Baldwin discloses wherein a determination is made to provide the person or caregiver with the notice in step (c). CenterWatch discloses providing a list of clinical study(ies) in accordance with a geographic location of a clinical study as

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discussed previously above (the Examiner interprets the geographic determination limitation to include the geographic location of the clinical trial the investigator is associated with). It would have been obvious to one of ordinary skill at the time of Applicant's invention to include the geographic location matching of CenterWatch with the determination step of Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As per claim 14, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources.

However, the Examiner takes official notice that it was well known in the electronic arts to provide information by telephone, mail or fax. The motivation was to provide the customer with customer preferred delivery methods particularly with highly sensitive information. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the features above within Baldwin, CenterWatch and Knight for the motivation stated above.

As to claim 130, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein said questionnaire is a pre-examination questionnaire

However, Knight discloses said questionnaire is a pre-examination questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a pre-examination questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 131, Baldwin and CenterWatch do not explicitly disclose the method of claim 130, wherein said pre-examination questionnaire is a screening questionnaire

However, Knight discloses said pre-examination questionnaire is a screening questionnaire . It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said pre-examination questionnaire is a screening questionnaire as disclosed by Knight within Baldwin, CenterWatch, and TVisions for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 132, Baldwin and CenterWatch do not explicitly disclose the method of claim 130, wherein said pre-examination questionnaire is a pre-screening questionnaire

However, Knight discloses said pre-examination questionnaire is a pre-screening questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a pre-examination questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 133, Baldwin and CenterWatch and do not explicitly disclose the method of claim 2, wherein said questionnaire is a pre-screening questionnaire

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However, Knight discloses said questionnaire is a pre-screening questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a pre-screening questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 134, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein said questionnaire is a screening questionnaire.

However, Knight discloses said questionnaire is a screening questionnaire (Fig. 7, paragraphs 79, 93, 94, 115-124). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a screening questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 135, Baldwin and CenterWatch do not explicitly disclose the method of claim 134, wherein said screening questionnaire is protocol specific.

However, Knight discloses said screening questionnaire is protocol specific (paragraph 78 and Fig. 23). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include wherein said questionnaire is a screening questionnaire as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

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As to claim 136, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein said questionnaire is designed for screening for clinically appropriate persons..

However, Knight discloses said questionnaire is designed for screening for clinically appropriate persons (paragraph 78 and Fig. 23). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said questionnaire is designed for screening for clinically appropriate persons as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 137, Baldwin, CenterWatch and TVisions do not explicitly disclose the method of claim 2, wherein said questionnaire requests information regarding inclusion/exclusion criteria

However, Knight discloses said questionnaire requests information regarding inclusion/exclusion criteria (paragraph 78 and Fig. 23). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include said questionnaire requests information regarding inclusion/exclusion criteria as disclosed by Knight within Baldwin and CenterWatch for the motivation of accelerating clinical trial recruitment (paragraph 50).

As to claim 138, the claim is similar in scope to claim 131 and is rejected on the same basis.

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As to claim 139 and 140, the claims are similar in scope to claim 138 and are rejected on the same basis.

As to claims 141-148, the claims are similar in scope to claims 130-137 and are rejected on the same basis.

As to claims 149-151, the claims are similar in scope to claim 138 and are rejected on the same basis.

6. Claims 3 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Knight as applied to claim 2 above, and further in view of "TVisions wins Top Web Externet Award; Recognized for Creative, Life-Saving Site" (hereinafter TVisions).

As per claim 3, Baldwin, CenterWatch, and Knight do not explicitly disclose The method of claim 2, further comprising the step of:

(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

However, TVisions discloses accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) (i.e. additions and updates to the patient profile database and the clinical trial databases activates the SecureNet Trial Matching System ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to

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include accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) as disclosed by TVisions within Baldwin, CenterWatch and Knight for the motivation of alerting physicians within seconds of possible matches of their patients with available or new clinical trials (page 2, second paragraph).

As per claim 129, Baldwin, CenterWatch and Knight discloses method for recruiting a person to participate as a subject in a clinical study as explained in claim 2 above.

Baldwin and CenterWatch and Knight do not explicitly disclose
(e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site.

However, TVisions allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site (i.e. additions and updates are to the patient profile database ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by TVisions for the motivation of alerting physicians within seconds of possible matches of their patients with available clinical trials and new clinical trials (page 2, second paragraph).

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Knight as applied to claim 2 above, and further in view of Larkin, Marilyn, "Physicians accelerate onto the Internet" (hereinafter Larkin).

As per claim 15, Baldwin and CenterWatch do not explicitly disclose The method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

However, Baldwin discloses wherein the step of automatically determining. Larkin discloses clinical studies directed to particular genetic sequences and using online recruitment (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the online patient recruitment of clinical studies for genetic studies within the Baldwin, CenterWatch and Knight method for the motivation of speeding up patient recruitment (i.e. within 6 months of the site's inauguration, 127 eligible woman ... By contrast, it took 4 years to recruit 395 volunteers with traditional methods ...)(see abstract and page 2)

(11) Response to Argument

a) Applicant's are entitled to their own Provisional Application's Filing Date, which removes Knight as a reference

The Examiner notes that the feature in question is

claim 2, step (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver

Appellant argues that although the phrase "automatically presenting questionnaires" does not appear in the '634 provisional application, the '634 provisional application does include a disclosure directed to support account sign-up and

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management, demographic capture, personalization of target audiences, and comparing trial criteria to “participant entered data” (see Appeal Brief, 6/14/04, page 7). Therefore, it would be difficult to contemplate that functionality absent presenting a questionnaire to the user (see Appeal Brief, page 8). The Examiner disagrees. The Examiner reviewed Appellant’s instant application for support of a questionnaire as claimed. In others, not whether a questionnaire was contemplated by Appellant’s claimed system but whether Appellant’s instant application disclosed the limitation of “automatically presenting a questionnaire *associated with the given clinical study* to the person or caregiver” (emphasis added). The Examiner could not find support for this feature in Appellant’s Provisional Application Number 60/178,634. Indeed, nowhere is such a limitation even suggested in the ‘634 Provisional Application. However, the Examiner did find support for this feature in Appellant’s instant application and the PCT filed on January 29, 2001. The Examiner noted in the previous non-final Rejection that this limitation would not be given the benefit of Appellant’s provisional application filing date (the other limitations of claim 2 were given the benefit of the priority date of Appellant’s provisional application).

Appellant’s argument that the Examiner’s conclusion that the claims were not entitled to the earlier filing date rested on an asserted lack of enablement by the provisional application is incorrect. Under 35 USC 119(e), the written description and drawing(s), if any, of the provisional application must adequately support and enable the subject matter claimed in the nonprovisional application that claims the benefit of the provisional application (see MPEP 201.11) The ‘637 provisional application lacks any

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support whatsoever of the limitation of "automatically presenting a questionnaire associated with the given clinical study to the person or caregiver". Furthermore, Appellant's arguments directed to the Examiner's use of the Colon reference and arguments set forth by the Examiner with respect to the Colon reference are moot since the rejections based on the Colon reference were withdrawn by the Examiner based on Appellant's arguments (see non-final rejection, mail date 2/27/04). Therefore, the Examiner was correct in denying the Appellant the benefit of filing date of Appellant's '637 provisional application with respect to the limitation of "automatically presenting a questionnaire associated with the given clinical study to the person or caregiver" and substantially similar limitations directed to presenting a questionnaire associated with the clinical study found in other claims.

b) Knight is not entitled to its Provisional Application Filing Date Because it lacks Common Inventorship, which removes Knight as a reference

The Examiner notes that there is a common inventor between the Provisional Application 60/227,484 and US 2002/0099570, namely Stephen C. Knight. A correction in inventorship in provisional application 60/227,484 was entered on 8/4/2004 adding Stephen C. Knight to the list of inventors. Therefore, there is a common inventor between the Provisional Application 60/227,484 and US 2002/0099570 and the 2002/0099570 properly claims benefit of the priority date of provisional application 60/227,484. Furthermore, since Knight was applied to limitations that did not receive the benefit of Appellant's provisional application filing date, knight was properly applied as prior art.

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c) Even if Knight is Prior Art, the Examiner has Improperly Combined References

i) The Rejection of Claims 2, 4, 4-14, and 130-151 under 35 USC 103, the cited motivation does not support the asserted combination

Appellant argues that the Examiner's use of five - seven references during the course of prosecution to overcome all the elements of the claims is powerful evidence of the non-obviousness of the claims. In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

Appellant argued that the motivation cited to combine the CenterWatch and Baldwin reference has nothing to do with the use of geographic information as claimed. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner notes that the motivation to combine was found directly in the references, specifically the CenterWatch reference (see non-final rejection, mail date 2/27/04, paragraph 9, pages 5-6). The Baldwin reference is directed to an automated

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online clinical trials patient matching system (see Baldwin, abstract) and provides information on clinical trials (page 2). The CenterWatch reference is directed to a web based Service for finding a variety of information related to specific clinical trials (see CenterWatch Clinical Trials Listing Service Home Page, page 1 of 4). Furthermore, CenterWatch states that the web site is designed to be used as a resource for patients interested in participating in clinical trials (see CenterWatch Clinical Trials Listing Service Home Page, page 1 of 4). Both references are in the same field of endeavor in that both are directed towards providing information on clinical trials in response to user requests. Furthermore, the geographic location feature of CenterWatch provides the requestor with the ability to indicate what region the requester is interested in (see CenterWatch Patient Notification Service, page 2 of 3). This allows the person or researcher to get the information on clinical trials that are of interest to them. Therefore, the motivation as cited by the Examiner is relevant to the element.

With respect to claims 10 and 13, in CenterWatch, the geographic location information is requested after a request for which therapeutic areas are of interest to the requester (see CenterWatch Patient Notification Service, pages 1 and 2 of 3). The plain meaning of the reference suggests that the service will limit information to clinical trials which match the therapeutic areas of interest indicated by the requester and the geographic location indicated by the requester.

Appellant further argues that the motivation to combine the Knight reference with the combination of Baldwin and CenterWatch is improper since the cited motivation has nothing to do with the limitation of automatically presenting a questionnaire associated

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with the given clinical study to the person or caregiver after step (d). The examiner disagrees. The Examiner notes that the motivation to combine was cited directly from the Knight reference(see non-final rejection, mail date 2/27/04, paragraph 9, page 6). The Knight reference is directed to an online system for recruiting patients into a clinical trial (see abstract). The cited motivation of accelerating clinical trial recruitment is directly related to this feature. The online system of Knight uses the questionnaire to determine if the patient might be eligible for the clinical trial (see figure 1). The use of the questionnaire is one of the tools disclosed by Knight to accelerate clinical trial recruitment. Therefore, the motivation as cited by the Examiner is relevant to the element.

ii) The Rejection of claims 3 and 129 under 35 USC 103, the cited motivation does not support the asserted combination

Appellant argues that the motivation to combine the TVisions reference with the combination of Baldwin, CenterWatch, and Knight is improper since the cited motivation has nothing to do with the limitation of accessing or amending information in the database. The Examiner disagrees. The Examiner notes that motivation to combine the TVisions reference with the combination of Baldwin, CenterWatch, and Knight was cited directly from the TVisions reference (see non-final rejection, mail date 2/27/04, paragraph 10, page 15). The TVisions reference is directed to an online clinical trials patient matching system (see page 1). The reference is in the same field of endeavor as discussed above for the Baldwin, CenterWatch and Knight references. The motivation is directly related to the claimed limitation in that any changes to the patient database and

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the clinical trials database results in activation of the matching system. In addition, physicians are notified within seconds of any matches based on changes made to the databases. It is unclear to the Examiner how a change to the patient database may be accomplished in the TVisions system without a subsequent visit to the web site by the physician. A change to patient information implies that original information on the patient existed in the patient database. Only the physician could have registered the patient by entering patient information and then only the physician subsequently amend that information as disclosed by TVisions.

iii) The Rejection of claim 15 under 35 USC 103, the cited motivation does not support the asserted combination

Appellant argued that the motivation to combine the Larkin reference within the Baldwin, CenterWatch and Knight combination is improper since the cited motivation has nothing to do with the limitation of accessing or amending information in the database. The Examiner disagrees. The Examiner notes that motivation to combine the Larkin reference with the combination of Baldwin, CenterWatch, and Knight was cited directly from the Larkin reference (see non-final rejection, mail date 2/27/04, paragraph 11, page 17). Larkin is directed to using the world wide web to obtain information on clinical trials (see page 1). The reference is in the same field of endeavor as discussed above for the Baldwin, CenterWatch and Knight references. In fact all of the references discuss solving the same problem, the long time it takes for patients and physicians to obtain clinical trial information and matching interested patients to available clinical trials. Larkin expressly discusses how quickly clinical trial information can be obtained

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from world wide web sources including one of the cited references, CenterWatch.

Moreover, Larkin includes in this discussion a web site for a gene discovery project (page 2). Therefore, the motivation as cited by the Examiner is relevant to the element.

c) Rejections based on alleged indefiniteness

i) The Examiner rejected Claim 14 as indefinite based on 35 USC 112, second paragraph for its reference to "and other off-line sources"

Appellant argues that the phrase "and other off line sources" was meant to capture the broad nature of the medium and not specific species of off-line medium and that the phrase could be easily understood by one of ordinary skill in the art at the time of Applicant's invention. The Examiner disagrees. The Examiner notes that Applicant claimed specific species of off-line sources within claim 14. Furthermore, the specification at page 37 and lines 7-8 lists the specific species of off line sources along with the phrase "or any off-line communication means". In listing specific off-line sources in the specification and claim 14 while also including the phrase and "other off-line sources" in the specification and claim 14, it is unclear what other off line sources the Appellant is trying to claim. Does this include only the off-line sources specifically listed, is it a group of off-line sources. Does it include off-line sources not contemplated at the time of Applicant's invention. The Examiner cannot determine the bounds of the claims. Therefore, the rejection of claim 14 based on 35 USC 112, second paragraph is proper.

i) The Examiner rejected Claim 15 as indefinite based on 35 USC 112, second paragraph for its reference to in the step of automatically determining further includes

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reference to genetic sequence information associated with a person registered in the database.

Appellant merely asserts that the claim is clear on its face. The Examiner explained why the claim would cause confusion to one of ordinary skill in the art (see non-final rejection, mail date 2/27/04, paragraph 7, page 3). Appellant has failed to explain why the claim is clear on its face or provide a citation from the specification that would clear up any confusion with respect to claim 15. Therefore, the rejection of claim 15 based on 35 USC 112, second paragraph is proper.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,


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January 5, 2005

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